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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SEAN GILES,

Plaintiff,

v.

ENDO PHARMACEUTICALS INC. and PROSTRAKAN GROUP PLC.,

Defendants.

CASE NO. **'14CV2196 JAH JLB**

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, Sean Giles, an individual, by and through his attorneys, herein files this Complaint against Defendants Endo Pharmaceuticals Inc. and Prostrakan Group PLC, states as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. PARTIES

1. Plaintiff Sean Giles ("Plaintiff") is a resident and citizen of San Diego, San Diego County, California.

2. Defendant Endo Pharmaceuticals Inc. (hereinafter "Defendant" or "Endo") is a corporation organized and existing under the laws of Delaware with its principal place of business at 1400 Atwater Drive, Malvern, PA 19355. At all relevant times, Endo Pharmaceuticals Inc. researched, developed, marketed, distributed and sold pharmaceutical products including Fortesta Gel ("Fortesta"), and was the holder of the exclusive right to commercialize Fortesta in the United States of America.

3. Defendant Prostrakan Group PLC. is a United Kingdom company with a place of business and a representative in the United States of America located at 685 Route 202/206, Suite 101, Bridgewater, New Jersey 08807. At all relevant times, Defendant Prostrakan Group PLC. was engaged in the research, development, sales and marketing of pharmaceutical products including Fortesta.

4. On information and belief, at all relevant times, Defendant Prostrakan Group PLC. provided and provides Defendant Endo with the exclusive license to commercialize Fortesta in the United States of America, and exclusively supplied and supplies Defendant Endo with Fortesta for the sale in the United States of America.

B. JURISDICTION AND VENUE

5. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because, inter alia, a substantial part of the events or omissions giving rise to the Plaintiff's claims occurred in, and because the Defendants transact business in, this district.

C. GENERAL INFORMATION

7. This case involves the prescription drug Fortesta, which is manufactured, sold, distributed and promoted by the Defendants as a testosterone replacement therapy.

8. Defendants misrepresented that Fortesta is a safe and effective treatment for hypogonadism and a condition they referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

9. Fortesta is an exogenous form of the androgen testosterone. It regulates the expression of platelet TXA_2 receptors in humans, which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

10. Fortesta is a hydroalcoholic gel containing testosterone. It is applied to the thighs. The drug enters the body through transdermal absorption.

11. Defendants failed to adequately warn physicians about the risks associated with Fortesta and the monitoring required to ensure their patients' safety.

12. Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for Fortesta. Further, Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low T", an abbreviated term for low testosterone.

13. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

14. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "LowT". Additionally, low testosterone is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

15. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially.

16. Consumers of Fortesta and their physicians relied on the companies false representations and were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

D. FACTUAL BACKGROUND

1. General Allegations

17. This action is for damages brought on behalf of the Plaintiff Sean Giles who was prescribed and supplied with, received and who has taken and applied the prescription drug Fortesta, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

18. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

19. At all times herein mentioned, the Defendants were engaged in the business of, or was successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Fortesta for the use and application by men, including, but not limited to, Plaintiff.

20. At all times herein mentioned, Defendants were authorized to do business within the state of California.

21. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

22. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of

this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug Fortesta is safe and free from serious side effects, and Defendants fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Regulatory History and Approved Uses

23. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

24. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

25. In men, testosterone levels normally begin a gradual decline after the age of thirty.

26. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

27. The Food and Drug Administration approved Fortesta in 2010 for the treatment of adult males who have low or no testosterone (a condition called Hypogonadism). After FDA approval, Fortesta was widely advertised and marketed by Defendants as a safe and effective testosterone replacement therapy.

28. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders and other conditions which cause suppression of gonadotropin-releasing hormone (GnRH).

29. Defendants' marketing strategy has been to aggressively market and sell Fortesta by misleading potential users about the prevalence and symptoms of low testosterone. Defendants failed to protect users from serious dangers that Defendants knew, or should have known, can result from the use of Fortesta.

30. Defendants successfully marketed Fortesta by undertaking campaigns designed to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical mental conditions, such as aging, stress, depression, and lethargy were actually attributed to low testosterone.

31. For example, in connection with the FDA approval of Fortesta, Defendants issued a press release claiming that "Low T affects nearly 14 million men in the United States, yet only 9 percent (1.3 million) of men diagnosed with Low T are receiving treatment for the condition." Defendants knew, or should have known, these assertions to be false, and had no reasonable grounds to believe them to be true.

32. Defendants' advertising programs sought to create the image and belief by consumers and their physicians that the use of Fortesta was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew, or should have known, these assertions to be false, and had no reasonable grounds to believe them to be true.

33. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendants deceived potential Fortesta users by overemphasizing and misrepresenting the prevalence and dangers of low testosterone, while downplaying known adverse and serious health effects of testosterone therapies including Fortesta.

34. Defendants concealed materially relevant information from potential testosterone users and minimized user and prescriber concern regarding the safety of Fortesta.

35. In particular, in the warnings Defendants gave and continue to give in their commercials, online and print advertisements, Defendants failed and fail to

mention significant side effects of Fortesta and had falsely represented and represent that Defendants have adequately tested it for all likely side effects.

36. Defendants did not provide adequate warnings to Plaintiff's doctors, Plaintiff, the healthcare community and the general public about the increased risk of serious adverse events that are described herein.

37. The product warnings for Fortesta in effect during the time period Plaintiff used Fortesta were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as Plaintiff of the serious risks associated with this drug.

38. As a result of Defendants' advertising and marketing, and representations about their products, men in the United States, including Plaintiff, pervasively sought out and seek out prescriptions for testosterone including Fortesta.

3. Adverse Events and Serious Health Risks Caused by TRT.

39. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

40. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be

delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

41. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[1] and serum estradiol levels[2]. It can also cause increased platelet aggregation and vasoconstriction.

42. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

43. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

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[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.

[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

44. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

45. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

46. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit

[4] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

47. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

48. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[8] An increase in blood viscosity is a known risk factor for ischemic heart disease[9], and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

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[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

49. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

50. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.

[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.

51. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

52. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.

53. In a case control study of men in the Framingham cohort *supra*, serum estradiol levels were significantly increased in subjects with coronary heart disease.[15]

54. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol. [16] Impaired contractile function results in numerous cardiovascular injuries and disease.

55. A study published in 2007 compared blood levels of testosterone and *estradiol* in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of *estradiol* in both groups of heart attack patients compared with those without coronary disease.[17] In another study, men admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients, *estradiol* levels in these heart attack patients were **180%** higher,

[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.

[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

[17] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.

while bioavailable testosterone levels were **nearly three times less** than those of control patients.[18]

56. High testosterone levels enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after MI, and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.[19]

57. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2has been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[20]

[18] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.

[19] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory PhysiologyPublished 1 May 2006**Vol.** 290**no.** H2043-H2050**DOI:** 10.1152/ajpheart.01121.2005

[20] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

58. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

59. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

60. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

61. In a study published in 2013[21], based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy

[21] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

among men lasting 12+ weeks reporting cardiovascular-related events, two reviewers independently searched, selected and assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

62. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

4. Inadequate Warnings and Labeling

63. Defendants' marketing strategy beginning in 2010 has been to aggressively market and sell their product by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its product.

64. Defendants promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

65. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendants deceived potential Fortesta users and their physicians by relaying positive information through the press, and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

66. Defendants concealed material relevant information from potential Fortesta users, and their physicians, and minimized user and prescriber concern regarding the safety of Fortesta, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

67. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represent that Endo adequately tested Fortesta for all

likely side effects. The Defendants also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

68. Fortesta's prescribing information and medication guide contained within the package materials do not warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

69. The prescribing information and medication guide contained within the package materials do warn that the use of the product may result in increased red blood cell count, but do not instruct physicians or patients that it can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count does not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor does it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%, including the fact that individuals with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

70. The prescribing information and medication guide contained within the package materials do instruct physicians to re-evaluate their patient's hematocrit 3 to 6 months after starting treatment, but they fail to warn patients and their physicians that the product can cause dangerous increases in hematocrit much

more rapidly, and also fail to instruct physicians to monitor their patient's hematocrit more frequently.

71. The prescribing information and medication guide contained within the package materials fail to state that testosterone replacement therapy should not be administered to men who have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant because the increase in serum estradiol caused by the drug can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.. They also fail to instruct physicians to screen all patients for underlying clotting traits before prescribing testosterone replacement therapy.

72. The prescribing information and medication guide contained within the package materials do warn that use of the product may result in risk of blood clots in the veins, but they specifically limit this warning to "blood clots in the legs" and only warn against blood clots in the legs that form as a result of increased red blood cell count (polycythemia). There is no warning for blood clots in the veins other than "blood clots in the legs", nor is there any warning of blood clots resulting from causes other than polycythemia. Also, there are no warnings that blood clots in veins as a consequence of polycythemia could result in

pulmonary embolism, or other injuries secondary to the formation of deep vein thrombosis in the legs or other parts of the body.

73. The prescribing information and medication guide contained within the package materials fail to warn that use of the product may result in elevated levels of estradiol. They do not instruct physicians to monitor estradiol levels, nor do they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There is also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

74. The prescribing information and medication guide contained within the package materials do not warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

75. The prescribing information and medication guide contained within the package materials do not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There is no

mention of the fact that there is a doubling of the risk of heart attacks in men over the age of 65 who use testosterone replacement therapy, despite the fact that the data supporting this finding has been available for years. Instead, the label only states that the manufacturer lacks any information regarding the safety or efficacy of testosterone therapy for men over the age of 65. This absence of a warning fails to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

76. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, et al. published as article in the Journal of the American Medical Association entitled Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels ["Vigen Paper"].

77. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

78. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, et al. published an article in PLOS ONE entitled Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men ["Finkle Paper"].

79. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

80. The increased incidence of heart attack and stroke was foreseeable at the time of the product launch of Fortesta.

81. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the United States Food & Drug Administration (FDA) announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

82. The marketing and promotion of the product to patients and physicians overstated its benefits by creating the impression that it was a safe and

effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

83. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Fortesta. If Plaintiff and his physician had known the risks and dangers associated with Fortesta, the physician would not have prescribed nor would Plaintiff would have taken Fortesta and consequently would not have been subject to its serious side effects; and/or, Plaintiff's physicians would have adequately monitored Plaintiff's hematocrit and estradiol levels, and, as a result, Plaintiff's injuries would have not otherwise have occurred

5. Fortesta Caused Plaintiff's Injuries

84. As a direct and proximate result of Defendants' conduct, Plaintiff's physician prescribed Fortesta to Plaintiff, and Plaintiff used Fortesta.

85. In choosing to take Fortesta, Plaintiff and Plaintiff's physician relied on claims made by Defendants that low testosterone is a disease that requires pharmaceutical drug treatment.

86. In choosing to take Fortesta, Plaintiff and Plaintiff's physician relied on claims made by Defendants that testosterone had been clinically shown to safely and effectively raise testosterone levels.

87. Had Plaintiff or Plaintiff's physician been adequately warned of the potential life-threatening side effects of Fortesta, Plaintiff would not have purchased or taken Fortesta.

88. As a result of using Fortesta, Plaintiff was caused to suffer continuing bodily injury, including (without limitations) a myocardial infarction, and was thus caused to sustain severe and permanent personal injuries, pain, suffering, and mental anguish.

II. CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

89. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

90. The Defendants is liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

91. The Fortesta manufactured and/or supplied by Defendants were defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

92. Defendants failed to adequately warn consumers and/or their health care providers that Fortesta could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

93. Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking Fortesta it was necessary to frequently monitor hematocrit and estradiol levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

94. The Fortesta manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Fortesta, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

95. As a direct and proximate result of Plaintiff's reasonably anticipated use of Fortesta as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

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Count Two – Negligence

96. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

97. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Fortesta.

98. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Fortesta to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular accident, deep vein thrombosis and it sequelae, pulmonary embolism, and sudden cardiovascular death.

99. Defendants had a duty of care when it undertook to provide comprehensive medical information to consumers and patients concerning "Low T" as a medical diagnostic entity; and, to educate and inform consumers and patients about "Low T;" and, to provide consumers and patients with the means for self-diagnostic screening and in-home testing for "Low T."

100. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of Fortesta to heart attack, stroke,

deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

101. Defendants' duty of care owed to consumers and patients included providing accurate, true, and correct information concerning:

-hypogonadism and its diagnostic criteria;

-the FDA-approved indications for the clinical use of the Fortesta product;

-the clinical safety and effectiveness profiles of Fortesta; and,

-appropriate, complete, and accurate warnings concerning the adverse effects of Fortesta, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

102. At all times herein mentioned, Defendants breached its duty of care by negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Fortesta and failed to adequately test and warn of the risks and dangers of Fortesta as described herein.

103. The Defendants negligently and carelessly disregarded the applicable regulations and industry standards regarding the prohibition against off-label marketing, misbranding and label expansion, and as a result millions of men, including the Plaintiff, were prescribed Fortesta unnecessarily, and therefore

needlessly exposed to serious health risks for which there were no or inadequate warnings.

104. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for Fortesta, including Plaintiff's prescribing physician. Specifically, the FDA had not approved Fortesta or any other testosterone-containing preparation for the treatment of "Low T."

105. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted the testosterone-containing product Fortesta with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

106. Despite the fact that Defendants knew or should have known that Fortesta caused unreasonable, dangerous side effects, Defendants continued to market Fortesta to consumers including Plaintiff, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that Fortesta marketing materials claim are caused by "Low T".

107. At all times material hereto, Defendants misbranded the Fortesta product on an on-going and continuous basis, and failed to warn physicians and patients that Fortesta was not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

108. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with Fortesta use.

109. As marketed, detailed, and promoted to physicians, including Plaintiff's prescribing physician, Defendants failed to warn that Fortesta caused, or increased the risk of harm of, cardiovascular and cerebrovascular injuries, including myocardial infarction and cerebrovascular accident, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

110. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

111. Defendants' negligence was a proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

Count Three – Breach of Implied Warranty

112. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

113. Prior to the time that the aforementioned products were used by the Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and

physicians that Fortesta was of merchantable quality and safe and fit for the use for which it was intended.

114. Specifically, the Defendants warranted to Plaintiff that its product was intended to treat a condition called "LowT" and that it was safe and fit for that use, but the Defendants failed to disclose that "LowT" is not a recognized medical condition and that its testosterone product was not FDA approved to treat any such condition.

115. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including Fortesta, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Fortesta. As a result, the Plaintiff used Defendants' product as it was warranted to be intended.

116. Fortesta was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Fortesta has dangerous propensities when used as intended and will cause severe injuries to users.

117. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Four - Breach of Express Warranty

118. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

119. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Fortesta was FDA approved to treat a condition called "LowT", and that it is safe, effective, fit and proper for its intended use. Plaintiff purchased Fortesta relying upon these warranties.

120. In utilizing Fortesta, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that there is no disease or medical condition called "LowT" that is recognized by any medical community, peer-reviewed journal, or learned treatise, and that Fortesta is unsafe and unfit for its purported intended uses.

121. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Five - Fraud

122. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

123. Through a sophisticated and well-orchestrated marketing campaign, the Defendants set out to invent a fictitious disease/medical condition that it called "LowT", and then purposely deceived the Plaintiff and his physicians into believing that this was a real disease/medical condition and that Plaintiff suffered from it. Defendants did this through marketing a set of generic and common conditions in middle-aged men, and representing that these conditions were "symptoms" of "LowT". Those commonly occurring conditions were listed in the "Is It LowT Quiz", and included:

- Being tired after dinner
- Diminished ability to play sports
- Lack of energy
- Being sad
- Being grumpy
- Decreased libido

Each of these purported "symptoms" of "LowT" are normal and common conditions for men over the age of 40, and especially common in men over the age of 50.

124. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Fortesta, and up to the present, knew that their product could cause an increase in hematocrit in patients to a level that more than doubles their risk for stroke, heart attack, and clot

formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of its product could result in a dramatic increase in serum estradiol levels, yet the Defendants willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Fortesta, which the Defendants had a duty to disclose.

125. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Fortesta and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Fortesta. Defendants knew of the foregoing, that Fortesta is not safe, fit and effective for human consumption, that using Fortesta is hazardous to health, and that Fortesta has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

126. Defendants knowingly, falsely, deceptively, and inaccurately designated the physiologic decrease in men's testosterone levels and the age-related symptoms men experience with aging as a form of acquired hypogonadism with the intent to deceive physicians into prescribing Fortesta; and, to drive increasing consumer and patient demand for Fortesta prescriptions.

127. Defendants knowingly, falsely, deceptively, and inaccurately designated and represented that the physiologic decline in men's testosterone levels and the age-related symptoms men experience with advancing age, as a form of "acquired hypogonadism" with the intent to confuse and deceive consumers and

patients, and to foster the belief by consumers and patients, including Plaintiff, that they harbored a "disease" or pathologic medical condition that was appropriately treated with the Fortesta product.

128. Defendants concealed and suppressed the true facts concerning Fortesta, and the actual disease for which it has been FDA approved to treat (Hypogonadism), with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe Fortesta, and Plaintiff would not have used Fortesta, if they were aware of the true facts concerning its dangers.

129. Defendants undertook to inform and educate consumers about the diagnostic hallmarks of "Low T," and engaged in and encouraged mass consumer screening for "Low T" via patient-directed questionnaires, quizzes, and information, as part of a mass marketing effort to encourage patients to seek treatment for "Low T," while having actual knowledge that Fortesta was not indicated for the treatment of "Low T," nor was it proven to be clinically safe and effective for treating "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

130. Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that it provided to consumers and patients through its multi-platform marketing, promotional, educational, and awareness campaigns concerning the Fortesta product and its indications for clinical use; and further knew that consumers and patients would make treatment

choices and exercise treatment options about their use of the Fortesta product in reliance upon this information.

131. Defendants deceived physicians by explicitly or implicitly claiming that the treatment of "Low T" was an FDA-approved clinical indication for use of Fortesta, when in fact it was an "off-label" indication for clinical use.

132. Consumers, including Plaintiff, required, and should have been provided with, truthful, accurate, and correct information concerning the FDA-approved indications for the clinical use for Fortesta and the clinical safety and effectiveness profiles for Fortesta, including information concerning the "off-label" use of the Fortesta product.

133. Plaintiff relied on the fraudulent and deceptive representations made by the Defendants to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that Fortesta was FDA approved to treat a condition called "LowT", and that the Defendants' testosterone drug was a safe and effective treatment for his "LowT".

134. Plaintiff would not have sought or continued treatment for "Low T" or administered Fortesta had he been provided with adequate, true, accurate, and correct information by Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of Fortesta, and the fact that "Low T" was not an FDA-approved indication for clinical use of Fortesta.

135. Plaintiff would not have sought or continued treatment for "Low T," or administered Fortesta, had he been provided with adequate, true, accurate, and correct information by Defendants, including information that there were no proven clinical profiles of safety or effectiveness for the use of Fortesta to treat "Low T."

136. During the detailing, marketing, and promotion to physicians, neither Defendants nor the co-promoters who were detailing Fortesta on behalf of Defendants warned physicians, including Plaintiff's prescribing physician, that Fortesta caused or increased the risk of harm of cerebrovascular accident and neurologic injuries.

137. Defendants, through its national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs, undertook to inform the consuming public and patients, including Plaintiff, about a "disease" Defendants denominated and characterized as "Low T."

138. These materials did reach Plaintiff, and he relied upon these materials in reaching his decision to purchase, use, and continue the use of Fortesta throughout his course of testosterone therapy.

139. Plaintiff would not have administered Fortesta to himself had the educational and informational materials made available to him by Defendants, and upon which he relied to his detriment, informed him about the risks of cardiovascular events and cerebrovascular accident with product use.

140. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

Count Six – Negligent Misrepresentation

141. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

142. From the time Fortesta was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that "LowT" was an actual disease/medical condition for which medical treatment was indicated, and that Fortesta was safe, fit, effective, and FDA approved for human consumption to treat "LowT". At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Fortesta and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

143. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians,

medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

144. The representations by the Defendants were in fact false, in that Fortesta is not safe, fit and effective for human consumption, using Fortesta is hazardous to health, and Fortesta has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

145. The foregoing representations by Defendants were made with the intention of inducing reliance and the prescription, purchase and use of Fortesta.

146. Plaintiff relied on the misrepresentations made by the Defendants to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that Fortesta was FDA approved to treat a condition called "LowT", and that the Defendants' testosterone drug was a safe and effective treatment for his "LowT".

147. In reliance of the misrepresentations by the Defendants, Plaintiff was induced to purchase and use Fortesta. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Fortesta. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

148. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Seven - Design Defect

149. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

150. Defendants participated in the manufacture, sale and marketing of an exogenous testosterone drug that was FDA approved to treat a specific medical condition called Hypogonadism, which is defined as a condition in which a male produces no or very low testosterone in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

151. The Defendants manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "LowT", which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the Defendants marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

152. Defendants manufactured, sold, and promoted this drug which contained a defective condition because the design was defective and unsafe in that it caused serious injuries and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

153. This design defect made the drug unreasonably dangerous, yet the Defendants knowingly introduced the drug into the market.

154. The drug as manufactured by the Defendants remained unchanged and was in the same condition at the time of the injury hereafter alleged.

155. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained permanent injury.

Punitive Damages Allegations

156. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

157. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Fortesta users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Fortesta. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

158. Prior to the manufacturing, sale, and distribution of Fortesta, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries.

Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Fortesta.

159. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Fortesta and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Fortesta. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Fortesta knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

160. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiff prays for judgment against the Defendants, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. For punitive or exemplary damages according to proof;

G. Restitution, disgorgement of profits, and other equitable relief;

H. Injunctive relief;

I. Attorney's fees;

J. For costs of suit incurred herein;

K. For pre-judgment interest as provided by law; and

L. For such other and further relief as the Court may deem just and proper.

DATED: September 15, 2014

CASEY GERRY SCHENK FRANCAVILLA BLATT & PENFIELD, LLP

By: s/Wendy M. Behan

WENDY M. BEHAN
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

DATED: September 15, 2014

CASEY GERRY SCHENK FRANCAVILLA BLATT & PENFIELD, LLP

By: s/Wendy M. Behan

WENDY M. BEHAN
Attorneys for Plaintiff

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Sean Giles

(b) County of Residence of First Listed Plaintiff San Diego, CA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Gayle M. Blatt & Wendy M. Behan
Casey Gerry Schenk Francavilla Blatt & Penfield, LLP
110 Laurel Street, San Diego, CA 92101 / (619) 238-1811

DEFENDANTS
Endo Pharmaceuticals Inc., Prostrakan Group PLC

County of Residence of First Listed Defendant Chester, PA
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)* '14CV2196 JAH JLB

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
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- ❒ 791 Employee Retirement Income Security Act

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- ❒ 462 Naturalization Application
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- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

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- ❒ 840 Trademark

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- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

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- ❒ 850 Securities/Commodities/ Exchange
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- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
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- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

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- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
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PRISONER PETITIONS

Habeas Corpus:
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- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

❒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332; 28 U.S.C. § 1391
Brief description of cause:
Product liability action related to testosterone products.

VII. REQUESTED IN COMPLAINT: ❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE Hon. Matthew F. Kennelly DOCKET NUMBER MDL No. 2545

DATE 09/15/2014 SIGNATURE OF ATTORNEY OF RECORD w/Wendy M. Behan

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.